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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,548	BAUER ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-21,31,35-45,47,49 and 75-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-21,31,35-45,47,49 and 75-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed September 7, 2007 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 76 and 79-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification on page 35, lines 3-9 discloses that four lines of diluted cotinine-tracer conjugate solution were applied 1 mm apart to the glass fiber pad at 1.5 ug/linear centimeter for each line. The application of the four lines was repeated and the pad dried for 1 hour at 37 degrees C in a drying oven. The applicant does not disclose the detectable tracer comprises a dried liquid nor does the applicant disclose the detectable tracer comprises multiple dried lines. There is no description in the specification disclosing the detectable tracer comprises a dried liquid nor is there a description disclosing the detectable tracer comprises multiple dried lines.

3. Claim 77 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification on page 24, lines 11-13 discloses that the mobilizable analyte-tracer conjugate (A-L-T) can be located beneath the application zone (covered by the sample pad), or distal to the application zone. The applicant does not disclose the sample application zone is a pad that completely overlaps the mobilization zone. There is no description in the specification that the sample application zone is a pad that completely overlaps the mobilization zone.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4-10, 76 and 79-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 depends from cancelled claim 3 and therefore it is unclear from which claim, claim 4 should depend. For examination purposes Examiner has interpreted claim 4 to depend from claim 1.

Claim 4 is vague and indefinite because it is unclear if the bibulous collection member is referring to the sample application zone or if the bibulous collection member is referring to something else. Also, it is unclear where this bibulous collection member is located in relation to the other structures recited in claim 1. Is the bibulous collection

member located before or after the sample application zone or is the bibulous collection member the application zone? Does applicant intend that the test strip further comprises an absorbent zone located at the end of the strip to aid in the movement of sample or does applicant intend something else?

Claim 8 depends from cancelled claim 3 and therefore it is unclear from which claim, claim 3 should depend. For examination purposes Examiner has interpreted claim 3 to depend from claim 1.

Claim 76 is vague and indefinite because it is unclear how the detectable tracer comprises a dried liquid. Does the detectable tracer surround or encapsulate a dried liquid? Is the dried liquid bound to the detectable tracer or does applicant intend something else?

Claim 79 is vague and indefinite because it is unclear how a detectable tracer comprises multiple dried lines of liquid. Are lines of liquid printed onto the detectable tracer and allowed to dry? Does the detectable tracer somehow contain a pattern of lines bound to the surface of the tracer? The specification on pages 35-36 and Figures 1-2 indicate a test strip comprising a line having detectable tracer within the line.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 2, 4, 5, 8-10, 12, 13, 20, 21, 31, 35, 36, 40, 41, 45, 49, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al (W0/98/39657) in view of Attridge (US 5,631,170).

Boehringer et al disclose a device and method for determining an analyte of interest. Boehringer et al disclose the device comprises a sample receiving zone (sample application area); a labeling zone (mobilization zone); and primary and secondary capture zone (Figure 1). Boehringer et al disclose that the labeling zone can comprise a labeled analyte analog. Boehringer et al disclose that the capture zones

comprise an immobilized specific binding pair member. Boehringer et al disclose that the analyte and labeled analyte analog (tracer molecule) compete for binding to the immobilized binding pair member. Boehringer et al also disclose that the sample flows sequentially past the capture zones (p. 16, lines 9-38). Boehringer et al disclose the flow matrix can be bibulous (p.16 & 31) and that the labeling zone (mobilization zone) is part of the matrix (p.4). Boehringer et al disclose that the bibulous material is porous and that the Boehringer pore size of the bibulous membrane is 1 to 20 microns (1000 to 20000 nm) (p. 32). Boehringer et al disclose that the sample is allowed to flow through the zones (p. 16). Boehringer et al discloses that the can also comprise microparticles coated with BSA (p. 42-43). Boehringer et al disclose that the sample can be saliva (p. 7). Boehringer et al also disclose that the device and components can be packaged in the form of a kit and that the kit can also contain instructions for performing the methods and interpreting the results (p. 36, lines

Boehringer et al differ from the instant invention in failing to teach the mobilization zone comprises a delayed release reagent.

Attridge discloses delayed release reagents added to the mobilization zone in competitive assays (col 5-col 6, & col 7 , lines 4-14). Attridge discloses that the delayed release reagent can be sucrose or polyvinyl alcohol (PVA) col 7 & 13). Attridge discloses that labeled analog and delayed release reagents can be used in devices such as test strips (col 5, lines 28-30). Attridge discloses that these delayed release reagents provides for an ideal opportunity to measure a reference signal and provides for more accurate referencing (col 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a delayed release reagent as taught by Attridge into the mobilization zone of Boehringer et al because both Attridge and Boehringer et al disclose competitive immunoassays and also both teach test strips and Attridge teaches that delayed release reagents provide for an ideal opportunity to measure a reference signal and provides for more accurate referencing.

With respect to the recitation "wherein the mobilization zone comprises a porous material to which the detectable tracer has been applied in the presence of a delayed release agent". This recitation is directed to a method of making a mobilization zone, and how a detectable tracer is applied to the mobilization zone is immaterial because the instantly recited claims are directed to a product (test strip) and even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different method. The combination of Boehringer et al and Attridge teaches the mobilization zone comprises a delayed release reagent and detectable tracer and therefore, the combination of references read on the instantly recited claim.

With respect to claim 2 as recited. Since Boehringer et al disclose the detectable tracer located in the same position as recited by applicant and since as stated above Boehringer et al and Attridge disclose the same structures and same reagents as

applicant has recited then the modified device of Boehringer selectively delays migration of the detectable tracer so that the detectable tracer reaches the primary capture area after the analyte reaches the primary capture area.

With respect to claim 4 as recited, Boehrigner et al disclose both sample and absorbent zones that comprise proximal and distal edges (pages 31-33 & Figs. 1-3). Therefore, Boehringer et al and Attridge read on the instant claim.

With respect to the percentages of the reagent as recited in claim 10, the optimum percentage of the reagent can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

2. Claims 6, 11 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Attridge in view of Fredrickson (US 6,001,658).

See above for the teachings Boehringer et al and Attridge.

Boehringer et al and Attridge differ from the instant invention in failing to specifically teach the biblous liquid collection member contains the mobilization zone,

primary capture area and secondary capture area. Boehringer et al and Attridge also fails to teach the detectable tracer is positioned beneath the surface of the test strip.

Frederickson teaches a nitrocellulose membrane comprising a conjugate pad (mobilization zone) and first and second capture areas (col 3- col 6). Frederickson also teaches detectable tracer impregnated (defined in Webster's as to permeate, permeate is also defined in Webster's as to penetrate or pass through) in a mobilization zone. Frederickson also teaches that the mobilization zone is located beneath the sample application zone. Therefore, Frederickson teaches that the tracer is beneath the surface of the test strip and also teaches the mobilization zone beneath the sample application zone. Frederickson also teaches the test strips are provided in dry form which allows for excellent storage and handling properties (col 1). Frederickson teaches that the membrane is specifically designed for lateral flow (col 6). Frederickson teaches the membrane and the impregnated detectable tracer provides for a rapid, volume, timing and temperature independent visually read test strip.

It would have been obvious to one or ordinary skill in the art at the time the invention was made to incorporate a membrane as taught by Frederickson into the modified device of Boehringer et al because Frederickson teaches that the membrane is specifically designed for lateral flow in test strips and also provides for a test strip with rapid, volume, timing and temperature independent visually read test strip.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to impregnate the detectable tracer of Boehringer et al as taught by Frederickson into the device and methods of Boehringer et al because Frederickson

teaches that this provides for a rapid, volume, timing and temperature independent visually read test strip. Further, the impregnation of labeled reagents within test strips is well known in the art and would have been obvious because it appears to be functionally equivalent (see previous office action of 03/07.07 listing references which disclose the impregnation of labeled reagents). Therefore, one of ordinary skill in the art would have a reasonable expectation of success impregnating the detectable tracer as taught by Frederickson into the device and methods of Boehringer et al.

3. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Attridge in view of Leuvering (US 4,313,734).

See above for teachings of Boehringer et al and Attridge.

Boehringer et al and Attridge differ from the instant invention in failing to specifically state that the detectable tracer comprises a visually detectable label covalently attached to analyte or an analyte analog.

Leuvering disclose particles (detectable tracer) coupled to reactive components. Leuvering disclose that the components can be coupled to the particles by covalent bonds (col 2). Leuvering disclose that these particles carry a charge (col 3) and that the particles can be combined with other reagents. Leuvering disclose that these particles can be visually detected (col 5). Leuvering disclose that the particles can be 100 nm (size which falls within the size disclosed by Applicant on page 21 of the specification). Leuvering disclose that these labels provide for method for the detection and/or determination of one or more components of the reaction between a specific binding

protein and the corresponding bindable substance in a test sample (col 1) and also proves to be more sensitive than known techniques (col 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate labels as taught by Leuvering into the device and methods of Boehringer et al because Boehringer et al specifically teaches that labels provided in Leuvering (US 4,313,734) are suitable labels for the device and methods of Boehringer (p. 34, lines 21-37) and also because Leuvering teaches that these labels provide for method for the detection and/or determination of one or more components of the reaction between a specific binding protein and the corresponding bindable substance in a test sample and also proves to be more sensitive than known techniques. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating the labels of Leuvering into the method and device of Boehringer et al.

With respect to claim 7 since the combination of Boehringer et al, Attridge and Leuvering disclose the same device and reagents as recited in the instant claims one of ordinary skill in the art would expect the detectable tracer to have a retarded migration rate relative to the migration of the analyte and to also posses a polarity or charge that interacts with the bibulous substrate.

4. Claims 15, 17-19, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Attridge in view of Fitzpatrick et al (US 5,451,504).

See above for the teachings of Boehringer et al and Attridge.

Boehringer et al and Attridge differ from the instant invention in failing to specifically teach the analytes.

Fitzpatrick et al disclose test strips, which will detect any antigen in which the appropriate reagents are used. Fitzpartrick et al disclose that the analyte can be drugs and small analytes of 100 to 1000 Daltons (col 4). Fitzpartrick et al disclose that detecting drugs or drug metabolites affects the choice of proper medical treatment and that the detection of drugs or drug metabolites in a person is also important in law enforcement.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to detect any analyte and incorporate the appropriate reagent such as taught by Fitzpatrick into the modified test strip and method of Boehringer et al because Fitzpatrick et al shows that the detection of analytes affects the choice of proper medical treatment.

5. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Attridge in view of Hardman et al (US 6,573,108).

See above for teachings of Boehringer et al and Attridge.

Boehringer et al and Attridge differs from the instant invention in failing to specifically teach the detectable tracer comprises a detectable tracer for an analyte comprising an antibody to HIV or Hepatitis.

Hardman et al teach reagents used in test strips for determining an analyte of interest. Hardman et al teaches that antibodies or antigens are used to determine the analyte of interest. Hardman et al teaches the analyte of interest can be HIV or

Hepatitis antigens and that one would use antibodies specific for the antigens in testing procedures (col 5, lines 10-37). Hardman et al teaches that this provides for determining for antigens of diagnostic significance.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate reagents such as taught by Hardman et al into the modified device and methods of Boehringer et al because Boehringer et al specifically teaches the analyte can be a virus (p. 8) and Boehringer et al is generic with respect to the virus and one of ordinary skill in the art would use the appropriate reagents to determine the analyte of interest in the case HIV. Further, Hardman teaches that these reagents provide for determining antigens of interest.

6. Claims 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Attridge in view of Thieme et al (US 5,871,905).

See above for the teachings of Boehringer et al and Attridge.

Boehringer et al and Attridge differ from the instant invention in failing to teach the saliva is combined with a bile acid or bile salt.

Thieme et al disclose the use of saliva as a liquid sample in immunoassays involving lateral flow immunochromatographic devices (col 1). Thieme et al disclose that the saliva is combined with a bile salt or acid (col 3, lines 19-25). Thieme et al disclose that the saliva sample combined with the bile acid or salt provides for methods of reducing false positives in assays for the detection of an analyte in an oral fluid sample. Thieme et al also disclose that a chelator such as EDTA can be impregnated into an absorbent pad and that a chelator can be stored within the assay device.

Thieme et al disclose that this chelator improves the effectiveness of the bile salt in reducing the incidence of false positives (col 15, lines 42-61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a bile acid or bile salt in combination with the saliva as taught by Thieme et al into the modified method of Boehringer et al because Thieme et al shows that the saliva sample combined with the bile acid or salt provides for methods of reducing false positives in assays for the detection of an analyte in an oral fluid sample.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a chelator such as taught by Thieme et al into the modified test strip and method of Boehringer et al because Thieme et al shows that a chelator such as EDTA can be impregnated into an absorbent pad and that a chelator can be stored within the assay device. Thieme et al disclose that this chelator improves the effectiveness of the bile salt in reducing the incidence of false positives.

7. Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Attridge in view Ledden et al (US 6,093,546).

See above for the teachings of Boehringer et al and Attridge.

Boehringer et al and Attridge differ from the instant invention in failing to teach the sample application zone completely covers the mobilization zone.

Ledden et al teaches that it is known in the art that a test strip can comprise an application pad (26, Fig. 2) completely covering mobilization zone (27, Fig. 2)(col 21,

example 10). Ledden et al disclose that this provides for a useful analytical apparatus, which can be used in determining an analyte in a sample (col 6, lines 11-16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an application pad as taught by Ledden et al into the modified test strip of Boehringer et al because Ledden et al shows that it is known in the art to construct a test strip having an application pad completely covering a mobilization zone and further because Ledden et al teaches that this provides for a useful apparatus which can be used in determining an analyte in a sample.

8. Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al and Attridge in view of Good et al (US 6,194,224) or Fredrickson (US 6,001,658).

See above for the teachings of Boehringer et al and Attridge.

Boehringer et al and Attridge differ from the instant invention in failing to teach the sample application zone is a pad that partially overlaps the mobilization zone.

Good et al disclose a test strip having a sample application pad which partially overlaps a conjugate pad (Figs. 1-2). Good et al that this aids in a test strip that provides for uniform and consistent results (col 2).

Fredrickson teaches a test strip having a sample application pad which partially overlaps a conjugate pad (Figs 1-2). Fredrickson teaches that this provides for a test strip that is useful for determining the presence or one or more components in a sample (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a sample pad which partially covers the conjugate pad as taught by Good et al into the modified test strip of Boehringer et al because Good et al shows that it is known in the art to incorporate a sample pad that partially covers the conjugate pad and also teaches that this aids in a test strip that provides for uniform and consistent results.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a sample pad which partially covers the conjugate pad as taught by Fredrickson into the modified test strip of Boehringer et al because Fredrickson shows that it is known in the art to incorporate a sample pad that partially covers the conjugate pad and also shows that this provides for a test strip that is useful for determining the presence or one or more components in a sample

Response to Arguments

9. Applicant's arguments filed September 7, 2007 have been fully considered but they are not persuasive.

Applicant argues that one skilled in the art would not consider making the proposed combination of Boehringer et al and Attridge. Applicant argues that Attridge clearly and repeatedly teaches that his test relies on a homogenous waveguide through which internal reflection must occur for the spectroscopy signal to be read. One skilled in the art would consider it counter-intuitive to even consider using a non-transparent, non-homogenous substrate of the type disclosed in Boehringer. This is not found persuasive because the Examiner has not relied upon Attridge for teaching waveguides

but rather has relied upon Attridge for teaching the use of delayed release agents in flow assays particularly those involving a test strip. And Attridge clearly teaches that these delayed release agents can be used in test strip assays (see above rejection). Applicant further argues that one skilled in the art would have no expectation of success that the capping layer of Attridge that provides a spectroscopic reference signal would have any function on the lateral flow test strip in Boehrigner because a bibulous porous lateral flow test strip in Boehringer is not transparent or homogenous and would not provide the required total internal reflection and the Boehringer substrate violates Attridge's explicit teachings about the required features of a good waveguide. This is not found persuasive because it appears applicant is incorporating a waveguide into the device of Boehringer et al and this is not the case. As stated above the Examiner has relied upon Attridge for teaching that it is known in the art to include delayed release agents in lateral flow assays such as test strips and the Examiner has combined Attridge with Boehringer et al (primary reference) for the incorporation of a delayed release agent into the test strip of Boehringer et al. Applicant's remaining arguments are a method of making the test strip. For example, applicant argues that "the mobilization zone comprises a porous material to which the detectable tracer has been applied in the presence of a delayed release agent". This is not found persuasive because as stated above in the office action the recitation "wherein the mobilization zone comprises a porous material to which the detectable tracer has been applied in the presence of a delayed release agent". This recitation is directed to a method of making a mobilization zone, and how a detectable tracer is applied to the mobilization zone is

immaterial because the instantly recited claims are directed to a product (test strip) and even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different method. The combination of Boehringer et al and Attridge teaches the mobilization zone comprises a delayed release reagent and detectable tracer and therefore, the combination of references read on the instantly recited claim.

Applicant remaining arguments under 103 have been considered but are considered moot in view of the new rejections and the amendments to the claims made by applicant.

Conclusion

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gary W. Counts
Examiner
Art Unit 1641
November 16, 2007

LONG V. LE 11/20/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600